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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,259	08/10/2000	Kersten M. Small	13092	7139

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EXAMINER
JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
1634	18

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/636,259	Applicant(s) SMALL ET AL.	
	Examiner Diana B. Johannsen	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-69* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

ELECTION/RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 and 62-65, drawn to polynucleotides, vectors, and host cells, classified in at least, for example, class 536, subclass 23.5, and class 435, subclasses 252.3, 320.1 and 325.

II. Claims 4-5, drawn to polypeptides, classified in at least, for example, class 530, subclass 350.

III. Claims 5-38 and 44-45, drawn to primers, probes, and methods of genotyping, classified in at least, for example, class 435, subclasses 6 and 91.2, and class 536, subclasses 24.31 and 24.33.

IV. Claims 39-43, drawn to methods of diagnosing disease, classified in at least, for example, class 435, subclass 6.

V. Claims 46-53, drawn to methods of predicting response to an agonist or antagonist, classified in at least, for example, class 435, subclass 6.

VI. Claims 54-61, drawn to methods of selecting a pharmaceutical composition, classified in at least, for example, class 435, subclass 6.

VII. Claims 66-67, drawn to transgenic animals, classified in at least, for example, class 800, subclass 13.

VIII. Claims 68-69, drawn to antibodies, classified in at least, for example, class 530, subclass 387.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-III and VII-VIII are drawn to patentably distinct products having different structures and functions. The nucleic acids encompassed by Inventions I and III are each composed of nucleotides linked by phosphodiester bonds. However, the polynucleotides, vectors and host cells of Invention I encode polypeptides, while the probes and primers of Invention III are short molecules that specifically amplify and/or detect a nucleotide polymorphism. Accordingly, the molecules of Inventions I and III differ both in structure and in function. The polypeptides of Invention II are composed of amino acids linked by peptide bonds and function in, e.g., methods of making antibodies. While the antibodies of Invention VIII are also composed of amino acids linked by peptide bonds, antibodies have a particular tertiary structure and binding properties that render them structurally and functionally distinct from the polypeptides of Invention II. The transgenic animals of Invention VII comprise nucleic acids, polypeptides, and antibodies, but are complex living organisms including numerous biomolecules and functioning in, e.g., production of heterologous polypeptides. Accordingly, the products of Inventions I-III and VII-VIII are patentably distinct.

Inventions III-VI are drawn to patentably distinct methods requiring different steps and/or having different objectives and effects. The methods of Invention III require steps of, e.g., primer extension or oligonucleotide hybridization to achieve the objective of genotyping. Invention IV requires steps of detecting a polymorphism to achieve an objective of disease diagnosis. Invention V requires a step of correlating a polymorphism with a response to achieve the effect of predicting the response of an individual to an agonist or antagonist. Invention VI requires a step of selecting a

pharmaceutical composition based on the presence of a polymorphism to achieve the objective of selecting an appropriate composition to administer to an individual with a disease.

Inventions I and III, I and IV, I and V, and I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides of Invention I may be used in a materially different process, such as methods of making protein.

Inventions III and IV, III and V, and III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the primers and probes of Invention III may be used in a materially different process, such as methods of detecting or cloning a gene encoding an alpha-2A adrenergic receptor.

Inventions II and III, II and IV, II and V, II and VI, VII and III, VII and IV, VII and V, VII and VI, VIII and III, VIII and VI, VIII and V, and VIII and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects

(MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides of Invention II are not disclosed as capable of use in the methods of Inventions III-VI and are employed in methods having different functions and effects, such as methods of making antibodies. Similarly, the transgenic animals of Invention VII are not disclosed as capable of use in the methods of Inventions III-VI, and are used in methods having different functions and effects, such as methods of producing heterologous polypeptides. The antibodies of Invention VIII are not disclosed as capable of use in the methods of Inventions III-VI, and are used in methods having different functions and effects, such as methods of detecting proteins.

Election Requirement Applicable to Group III

Group III encompasses multiple pairs of primers, as recited in, e.g., claims 17 and 26. The various primers and pairs claimed have different nucleotide sequences, and therefore different structures. Further, the specification discloses at, e.g., page 56, that the primer pairs of the claims amplify different portions of the alpha 2A gene, and further include universal sequencing primers. Thus, the various primer pairs encompassed by the claims differ both structurally and functionally. Accordingly, a further restriction is applied to Group III. If Group III is elected, **Applicant is further required to elect** a single primer pair. Applicant should specifically identify the SEQ ID Nos corresponding to the elected pair.

This is not an election of species. Applicant is advised that examination will be restricted to only the elected primer pair.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, and because Inventions I-VIII, as well as the various primer pairs of Invention III, require different sequence and text searches that are not co-extensive, examination of these distinct Inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers

for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
December 16, 2002